

SUBCHAPTER F—MANDATORY INSPECTION OF FISH OF THE ORDER SILURIFORMES AND PRODUCTS OF SUCH FISH

PART 530—GENERAL REQUIREMENTS; DEFINITIONS

Sec.

530.1 General.

530.2 FSIS organization for fish inspection.

530.3 Access to establishments.

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 530.1 General.

(a) The regulations in this subchapter provide for the inspection of Siluriformes fish and fish products. The inspection and regulations are intended to prevent the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce of any fish or fish product that is capable of use as human food and is adulterated or misbranded at the time of the sale, transportation, offer for sale or transportation, or receipt for transportation.

(b) Fish as defined in this subchapter are amenable to the Act, including, as the Administrator may determine, to provisions of the Act in which other amenable species are named, except where the Act specifically excludes the provisions from applicability to fish.

§ 530.2 FSIS organization for inspection of fish and fish products.

The Food Safety and Inspection Service, U.S. Department of Agriculture, administers an inspection program for fish and fish products. The organization of FSIS and the principal offices of FSIS and their functions are described, and organizational terms defined, in 9 CFR part 300, subchapter A of this chapter. Section 300.3 lists the FSIS district offices and the geographic areas of the districts.

§ 530.3 Access to establishments.

The provisions of 9 CFR 300.6 apply to fish processing establishments and related industries as they do to other establishments subject to the FMIA.

PART 531—DEFINITIONS

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 531.1 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 106 Stat. 4499, 119 Stat. 2166, 122 Stat. 1369, 122 Stat. 2130, 21 U.S.C., sec. 601 *et seq.*)

Adulterated. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the

meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, That an article which is not deemed adulterated under paragraphs (2)(ii), (iii), or (iv) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefore; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Amenable species. A species that is, and whose products are, subject to the Act and regulations promulgated under the Act, except as the Act may provide.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from the carcass or parts or products of the carcass of any amenable species, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Feeds for amenable species manufactured from processed by products of amenable species.

Applicant. Any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. Any substance, including metabolites, remaining in fish at time of slaughter or in any of their tissues after slaughter as the result of treatment or exposure of the fish to a pesticide, organic or inorganic compound, hormone, hormone like substance, anthelmintic, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass or part or product of a carcass of any fish unless it is denatured or otherwise identified as required by § 540.3 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., barbels or fins in their natural state.

Carcass. All parts, including viscera, of any slaughtered livestock.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consumer package. Any container in which a fish product is enclosed for the purpose of display and sale to household consumers.

Container. Any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Dead fish. The body of a fish that has died otherwise than by slaughter.

Dying or diseased fish. Fish affected by any of the conditions for which the fish are required to be condemned under part 539 or other regulations in this subchapter.

Edible. Intended for use as human food.

Farm-raised. Grown under controlled conditions, within an enclosed space, as on a farm.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Fish. (1) For the purposes of this subchapter, any fish of the order Siluriformes, whether live or dead.

(2) The skeletal muscle tissue of fish. As applied to products of fish of the order Siluriformes, this term has a meaning comparable to that of “meat” in the meat inspection regulations (9 CFR 301.2).

Fish byproduct. Any fish part capable of use as human food, other than the skeletal muscle tissue, that has been derived from one or more fish.

Fish food product. Any article capable of use as human food that is made wholly or in part from any fish or part thereof; or any product that is made wholly or in part from any fish or part thereof, excepting those exempted from definition as a fish product by the Administrator in specific cases or by a regulation under one or more of the following circumstances: (1) If its labeling is false or misleading in any particular; (2) If it is offered for sale under the name of another food; (3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and immediately thereafter, the name of the food imitated; (4) If its container is so made, formed, or filled as to be misleading; (5) If in a package or other container unless it bears a label showing: (i) The name and place of business of the manufacturer, packer, or distributor; and (ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents; (6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

Fish product. Any fish or fish part; or any product that is made wholly or in part from any fish or fish part, except for those exempted from definition as a fish product by the Administrator in a regulation in this subchapter. Except where the context requires otherwise (e.g., in part 540 of this subchapter), this term is limited to articles capable of use as human food.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Inedible. Adulterated, uninspected, or not intended for use as human food.

“Inspected and passed” or “U.S. Inspected and Passed” or “U.S. Inspected

and Passed by Department of Agriculture” (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Misbranded. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (7)(ii) of this definition unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the man-

ner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of fish food and fish products excluding labeling and packaging materials as covered in part 541 of this subchapter.

Official certificate. Any certificate prescribed by the regulations in this subchapter for issuance by an inspector or other person performing official functions under the Act.

Official device. Any device prescribed by the regulations in part 312 of this subchapter for use in applying any official mark.

Official establishment. Any slaughtering, cutting, boning, fish product canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in this section, where inspections are authorized to be conducted as prescribed in part 557 of this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article, fish, or fish product under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for fish products.

Person. Any individual, firm, or corporation.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for purposes of the Act and the regulations in this subchapter as under the Federal, Drug, and Cosmetic Act.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Process authority. A person or organization with expert knowledge in fish production process control and relevant regulations. This definition does not apply to §548.6 of this subchapter or to subpart G of part 318 of this chapter.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to §548.6 of this subchapter or to subpart G of part 318 of this chapter.

Producer. Any person engaged in the business of growing farm-raised fish.

Product. Any carcass, fish, fish product, or fish food product, capable of use as human food.

Program. The organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Slaughter. With respect to fish, intentional killing under controlled conditions.

State. Any State of the United States or the Commonwealth of Puerto Rico.

Territory. Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States.

U.S. Condemned. This term means that the fish, part, or product of fish so identified was inspected and found to be adulterated and is condemned.

U.S. Detained. This term applies to fish, fish products, and other articles which are held in official custody in accordance with section 402 of the Act (21 U.S.C. 672), pending disposal as provided in the same section 402.

U.S. Retained. This term means that the fish, part, or product of fish so identified is held for further examination by an inspector at an official establishment to determine its disposal.

United States. The States, the District of Columbia, and the Territories of the United States.

[80 FR 75616, Dec. 2, 2015]

PART 532—REQUIREMENTS FOR INSPECTION

Sec.

532.1 Establishments requiring inspection.

532.2 Application for inspection; information to be furnished; grant or refusal of inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

532.3 Exemption of retail operations.

532.4 Inspection at official establishments; relation to other authorities.

532.5 Exemption from definition of fish product of certain human food products containing fish.

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§532.1 Establishments requiring inspection; other inspection.

(a) No establishment may process or prepare fish, fish parts, or fish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without inspection under these regulations, except as expressly exempted in §532.3.

(b) Inspection under the regulations is required at:

(1) Every establishment, except as provided in the regulation on exemption of retail operations (§532.3), in which any fish or fish products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food.

(2) Every establishment, except as provided in the regulation on exemption of retail operations (§532.3), within any State or organized territory which is designated pursuant to section 301 of the Act (21 U.S.C. 661), at which any fish or fish products are processed for use as human food solely for distribution within that State or territory.

(3) Except as provided in the regulation on exemption of retail operations (§532.3), every establishment designated by the administrator under

section 301 of the Act (21 U.S.C. 661) as one producing adulterated fish products which would clearly endanger the public health.

(4) *Coverage of fish and fish products processed in official establishments.* All fish and fish products prepared in an official establishment must be inspected, handled, processed, marked, and labeled as required by the regulations.

(5) *Other inspection.* Periodic inspections may be made of:

(i) The records of all persons engaged in the business of hatching, feeding, growing, or transporting fish between premises where fish are bred, hatcheries, and premises where fish are grown, and from these premises to processing establishments.

(ii) Exempted retail establishments to determine that those establishments are operating in accordance with these regulations.

§ 532.2 Application for inspection; information to be furnished; grant or refusal of inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

(a) Application for inspection is as required by 9 CFR 304.1.

(b) Information to be furnished is as required by 9 CFR 304.2(a), (b), and (c)(1). Conditions for receiving inspection, including having written Sanitation SOPs, HACCP plans and written recall procedures, are as required by 9 CFR 304.3.

(c) *Official numbers; inauguration of inspection; withdrawal of inspection; reports of violation.* The requirements for assignment of official numbers, inauguration of inspection, withdrawal of inspection, and reports of violations at fish processing establishments are as required by part 305 of this chapter for meat establishments.

(d) *Assignment and authorities of program employees.* The requirements concerning the assignment and authorities of Program employees at fish processing establishments are as required by parts 306 and 307 of this chapter with respect to Program employees at meat establishments.

§ 532.3 Exemption of retail operations.

(a) The exemption in 9 CFR 303.1(d) for operations of types traditionally and usually conducted at retail stores and restaurants applies with respect to fish products as it does with respect to products of other amenable species under the FMIA.

(b) The exemption also applies to the slaughtering of fish conducted at and by the operator of a retail store or restaurant, with respect to live fish purchased by a consumer at the retail store or restaurant, in accordance with the consumer's instructions.

(c) A retail quantity of fish or fish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds and the quantity of fish or fish product sold by a retail supplier to a non-household consumer is a normal retail quantity if it does not exceed 150 pounds in the aggregate.

§ 532.4 Inspection at official establishments; relation to other authorities.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official establishment that are in addition to or different than those made under this subchapter may not be imposed by any State or local jurisdiction except that the State or local jurisdiction may impose recordkeeping and other requirements within the scope of § 550.1 of this subchapter, if consistent with those requirements, with respect to the establishment.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this subchapter, the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to any fish or fish products processed at any official establishment in accordance with the requirements under this subchapter and those Acts.

§ 532.5 Exemption from definition of fish product of certain human food products containing fish.

The following articles contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers to be

products of the fish food products industry. Therefore, the articles are exempted from the definition of “fish product” and the requirements of the Act and the regulations that apply to fish products, if they comply with the conditions specified in this section.

(a) Any human food product if:

(1) It contains less than 3 percent raw or 2 percent cooked fish;

(2) The fish ingredients used in the product were prepared under Federal inspection or were inspected under a foreign inspection system approved under §557.2 of this subchapter and imported in compliance with the Act and the regulations;

(3) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(4) The product is not represented as a fish product. The percentage of cooked fish ingredients must be computed on the basis of the moist, deboned, cooked fish in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) A product exempted under this section will be deemed to be represented as a fish product if the term “fish” or a term representing a fish species that is covered by the definition of “fish” in part 531 of this subchapter is used in the product name of the product without appropriate qualification.

(c) A product exempted under this section is subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

PART 533—SEPARATION OF ESTABLISHMENT; FACILITIES FOR INSPECTION; FACILITIES FOR PROGRAM EMPLOYEES; OTHER REQUIRED FACILITIES

Sec.

533.1 Separation of establishments.

533.2 [Reserved]

533.3 Facilities for Program employees.

533.4 Other facilities and conditions to be provided.

533.5 Schedule of operations.

533.6 Overtime and holiday inspection service.

533.7 Basis of billing for overtime and holiday services.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§533.1 Separation of establishments.

Each official establishment shall be separate and distinct from any unofficial establishment and from any other official establishment, except an establishment preparing products under the FMIA, the PPIA, or the EPIA, or under State fish inspection requirements and authorities that are deemed to be at least equal to those provided under the FMIA. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe. An official establishment that is not separate and distinct from another official or unofficial establishment must ensure that no sanitary hazards are created by the lack of separation.

§533.2 [Reserved]

§533.3 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, must be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the District Manager or the frontline supervisor and must be conveniently located, properly ventilated, and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such facilities are deemed necessary by the frontline supervisor. At the discretion of the Administrator, small establishments requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing must be provided by each establishment.

§ 533.4 Other facilities and conditions to be provided.

When required by the District Manager or the frontline supervisor, each official establishment must provide the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions:

(a) Sufficient light to be adequate for the proper conduct of inspection;

(b) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(c) Receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned and to be marked in a conspicuous manner with the phrase "U.S. Condemned" in letters not less than 2 inches high, and, when required by the frontline supervisor, to be equipped in a way that allows the receptacles to be locked or sealed;

(d) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in handling diseased carcasses, for cleaning and sanitizing floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(e) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter;

(f) Docks and receiving rooms, to be designated by the operator of the official establishment, with the frontline supervisor, for the receipt and inspection of fish, fish products, or other products.

(g) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) can be stored. Official certificates shall be kept when not in use in suitable file cabinets. All such lockers and file cabinets shall be equipped for sealing or locking with locks or seals to be supplied by the Department. The keys of such locks shall not leave the custody of Program employees.

§ 533.5 Schedule of operations.

The requirements governing the schedule of operations for fish processing establishments are as required by 9 CFR 307.4 for meat establishments.

§ 533.6 Overtime and holiday inspection service.

The requirements governing overtime and holiday inspection service in 9 CFR 307.5 apply to fish processing establishments.

§ 533.7 Basis of billing for overtime and holiday services.

The requirements for billing and overtime and holiday inspection services are as required by 9 CFR 307.6.

PART 534—PRE-HARVEST STANDARDS AND TRANSPORTATION TO PROCESSING ESTABLISHMENT

Sec.

534.1 General.

534.2 Water quality for food fish.

534.3 Standards for use of drugs in the raising of fish.

534.4 Transportation to processing plant.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 534.1 General.

Fish that are harvested for use as human food must have grown and lived under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food.

§ 534.2 Water quality for food fish.

Farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals that may contaminate fish. FSIS will collect samples of feed, fish, and water from producers, at intervals to be determined by the Administrator, for the purpose of verifying that fish are being raised under conditions that will yield safe, wholesome products.

§ 534.3

§ 534.3 Standards for use of drugs in the raising of fish.

New animal drugs that are the subject of an approved new animal drug application (NADA) or abbreviated new animal drug application (ANADA) under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b), or a conditional approval under section 571 of the Act (21 U.S.C. 360ccc), or an investigational exemption under section 512(j) of the Act (21 U.S.C. 360b(j)) may be used in the raising of fish. New animal drugs approved under section 512 of the Act may be used in an extra-label manner if such use complies with section 512(a)(4) of the Act and FDA regulations found at 21 CFR part 530.

§ 534.4 Transportation to processing plant.

A vehicle used to transport fish from a producer's premises to a processing establishment must be equipped with vats or other containers for holding the fish. The vats or other containers must be maintained in a sanitary condition. Sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that fish delivered to the processing establishment will not be adulterated. Any fish that are dead, dying, diseased, or contaminated with substances that may adulterate fish products are subject to condemnation at the official fish processing establishments.

PART 537—SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS; NOTIFICATION REGARDING ADULTERATED OR MISBRANDED PRODUCTS

Sec.

537.1 Basic requirements.

537.2 Hazard analysis and HACCP plan.

537.3 Notification.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 537.1 Basic requirements.

(a)(1) Any official establishment that prepares or processes fish or fish prod-

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ucts for human food must comply with the requirements contained in 9 CFR parts 416, Sanitation and 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this subchapter.

(2) For the purposes of 9 CFR part 416, Sanitation; 9 CFR part 417, Hazard Analysis and Critical Control Point (HACCP) Systems; and 9 CFR part 500, Rules of Practice, an “official establishment” or “establishment” includes a plant that prepares or processes fish or fish products.

§ 537.2 Hazard analysis and HACCP plan.

(a) A fish establishment's hazard analysis shall take into account the food safety hazards that can occur before, during, and after harvest.

(b) The failure of an establishment to develop and implement a hazard analysis and a HACCP plan that comply with this part or to operate in accordance with the requirements of 9 CFR Chapter III, Subchapter E, will render the products produced under these conditions adulterated.

§ 537.3 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded fish product received by or originating from the official establishment has entered commerce, in accordance with the requirements of 9 CFR part 418.

PART 539—MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS RESPECTING PHYSICAL, CHEMICAL, OR BIOLOGICAL CONTAMINANTS

Sec.

539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.

539.2 Physical, chemical, or biological contaminants.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.

(a)(1) Carcasses or parts of fish affected by abscesses or lesions, zoonotic and non-zoonotic parasites such as cestodes, or such parasites as digenean trematodes, metacercaria (*Bolbophorus* spp.), yellow grubs (*Clinostomum* spp.), or white grubs (*Hysteromorpha* spp.) are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(2) Fish affected by Heterophyid intestinal flukes or *Dictophymatidae* nematodes are subject to condemnation unless properly disposed of by the establishment.

(b) Fish affected by diseases, including columnaris (infection by *Flavobacterium columnare*/*Flexibacter columnaris*) and enteric septicemia of fish (ESC), are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(c) Fish carcasses or parts or fish products that are found to be in a state of spoilage or decomposition are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(d) Fish with unusual gross deformities caused by disease or chemical contamination may not be used for human food.

§ 539.2 Physical, chemical, or biological contaminants.

(a) Fish and fish products that are contaminated with physical matter are subject to official retention and condemnation.

(b) Antibiotic or other drug residues in fish tissues must be within applicable tolerances in 21 CFR part 556 or within an applicable import tolerance established under 21 U.S.C. 360b(a)(6).

(c) Pesticide residues in fish tissues must be within applicable tolerances in 40 CFR part 180.

(d) Fish or fish products containing violative concentrations of drugs or other chemicals are subject to condemnation.

PART 540—HANDLING AND DISPOSAL OF CONDEMNED AND OTHER INEDIBLE MATERIALS

Sec.

540.1 Dead fish.

540.2 Specimens for educational, research, and other nonfood purposes; permits.

540.3 Handling and disposal of condemned or other inedible materials.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 540.1 Dead fish.

(a) With the exception of dead fish that have died en route to an official establishment that have been received with live fish at the official establishment, and that are subject to sorting and disposal at the official establishment, no fish or part of the carcass of fish that died otherwise than by slaughter may be brought onto the premises of an official establishment without advance permission from the FSIS frontline supervisor.

(b) The official establishment shall maintain physical separation between slaughtered fish and the edible parts or products of slaughtered fish and any fish or parts of fish that have died otherwise than by slaughter. Fish or any parts of fish that have died otherwise than by slaughter shall be excluded from any room or compartment in which edible product is prepared, handled, or stored.

§ 540.2 Specimens for educational, research, and other nonfood purposes; permits.

The requirements of 9 CFR 314.9 apply to the handling and release of specimens of condemned or other inedible fish materials.

§ 540.3 Handling and disposal of condemned or other inedible materials.

Condemned or other inedible fish and fish parts shall be separated from edible fish. If not disposed of on the premises of the establishment, the condemned and inedible fish parts shall be conveyed from the official establishment for disposition at a rendering plant, an animal feed manufacturing

establishment, or at another establishment for other non-food use. If not decharacterized by use of approved denaturants or colorings, the inedible materials shall be enclosed in containers that are conspicuously marked to indicate that the contents are condemned or otherwise inedible. The materials may be shipped under company or official seal to a rendering facility or for other inedible processing.

PART 541—MARKS, MARKING AND LABELING OF PRODUCTS AND CONTAINERS

Sec.

541.1 General.

541.2 Official marks and devices to identify inspected and passed fish and fish products.

541.3 Official seals for transportation of products.

541.4 Official export inspection marks, devices, and certificates.

541.5 Official detention marks and devices.

541.7 Labels required; supervision of a Program employee.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 541.1 General.

The marks, devices, and certificates prescribed or referenced in this part are official marks, devices, and certificates for the purposes of the Act respecting fish and fish products. The marks, devices, and certificates shall be used only in accordance with the regulations in this part.

§ 541.2 Official marks and devices to identify inspected and passed fish and fish products.

(a)(1) The official inspection legend required by this part must be shown on all labels for inspected and passed fish and fish products and must be in the following form prescribed in 9 CFR 312.2(b)(1) for inspected and passed products of cattle, sheep, swine, and goats, or in another form to be prescribed by the Administrator, except that it need not be of the size illustrated, if it is of a sufficient size and color to be conspicuously displayed, and readily legible, and in the same proportions of letter size and boldness are maintained as illustrated:



(2) The official inspection legend shall contain the words “U.S. Inspected and Passed” or an abbreviation of those words approved by the Administrator.

(b) This official mark must be applied by mechanical means and must not be applied by a hand stamp.

(c)(1) The official inspection legend, or the approved abbreviation of the legend, must be printed on consumer packages and other immediate con-

tainers of inspected and passed fish products or on labels to be securely affixed to the containers of the products and may be printed or stenciled on the containers but must not be applied by rubber stamping.

(2) The official inspection legend may also be used for the purposes of marking shipping containers, band labels, and other articles with the approval of the Administrator.

(d) Whole gutted fish carcasses that have been inspected and passed in an official establishment and are intended for sale as whole gutted fish must be marked with the official inspection legend or properly packaged in an immediate container labeled with the official inspection legend and all other

required labeling features, that will ensure that the fish carcasses are identified as “Inspected and Passed” and will not become misbranded while in commerce. The official inspection legend used for this purpose must be in the form illustrated below or in another form determined by the Administrator:



§ 541.3 Official seals for transportation of products.

The official mark for use in sealing railroad cars, cargo containers, or other means of conveyance as prescribed in part 555 of this subchapter must be the inscription and serial number shown in 9 CFR 312.5 or another official mark approved by the Administrator. Any seal approved by the Administrator for applying the official mark is an official device for the purposes of the Act. The seal must be attached to the means of conveyance only by a Program employee, who shall also affix a “Warning Tag” (Form MP-408-3 or similar official form).

§ 541.4 Official export inspection marks, devices, and certificates.

(a) The official export inspection mark for fish required by part 552 of this subchapter must be in the same form as that specified in 9 CFR 312.8(a) or otherwise as prescribed by the Administrator.

(b) The official export certificate for fish and fish products required by part 552 must be in the same form as that prescribed for meat and meat food products in 9 CFR 312.8(b) or otherwise as prescribed by the Administrator.

§ 541.5 Official detention marks and devices.

The official mark for shipments of articles and fish detained under this

subchapter is the designation “U.S. Detained,” and the official device for applying the mark is the official “U.S. Detained” tag (FSIS Form 8400-2) as prescribed in 9 CFR 329.2 or otherwise by the Administrator.

§ 541.7 Labels required; supervision of a Program employee.

(a) *General labeling requirements.* The requirements in part 317, subpart A, of this chapter, governing labels and labeling, safe-handling labeling, abbreviations of official marks, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, re-labeling of products, the storage and distribution of labels, and the requirements for packaging materials, apply to fish and fish products.

(b) A country of origin statement on the label of any fish “covered commodity” as defined in 7 CFR part 60, subpart A, that is sold by a “retailer,” as defined in 7 CFR 60.124, must comply with the requirements of 7 CFR 60.200 and 60.300.

(c) The safe handling instructions required on labels of fish and fish products specified in paragraph (a) of this section shall replace statements that include the terms “meat” and “poultry” with the following:

(1) In the rationale statement, “This product was prepared from inspected

and passed fish. Some food products may contain bacteria that could cause illness if the product is mishandled and cooked improperly. For your protection, follow these safe handling instructions.” This statement shall be placed immediately after the heading and before the safe handling statements.

(2) In the labeling statements, “Keep raw fish separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish. (A graphic illustration of soapy hands under a faucet shall be displayed next to statement.)”

(d)(1) Labels and labeling of fish in the order Siluriformes and the products of those fish must bear the appropriate common or usual names of the fish. For example, among fish in the family Pangasiidae, the labels and labeling for fish of the species *Pangasius bocourti* must bear the term “basa”; for the species *Pangasius hypophthalmus* or *Pangasionodon hypophthalmus*, “swai,” “tra,” or “sutchi.”

(2) The labels and labeling only of fish and fish products within the family Ictaluridae may bear the term “catfish.”

(e) The requirements in part 441 of this chapter, governing water retained from processing in raw meat and poultry, apply to retained water in fish. The requirements in part 442 of this chapter, governing quantity of contents labeling, the testing of scales, and the handling of product that is found to be out of compliance with net weight requirements, apply to fish and fish products.

(1) Packages of frozen or fresh-frozen fish carcasses or parts must be labeled to reflect 100-percent net weight after thawing. The de-glazed net weight must average 100 percent of the stated net weight of the frozen product when sampled and weighed according to the method prescribed in National Institute of Standards and Technology (NIST) Handbook 133 Chapter 2, Section 2.6.¹

(2) [Reserved]

¹U.S. Department of Commerce. NIST Handbook 133: Checking the Net Contents of Packaged Goods, 2013. Washington, DC.

(f) *Nutrition labeling.* The requirements for nutrition labeling of meat and meat food products in part 317, subpart B, of this chapter, also apply to the labeling of fish and fish food products.

(g) *Label approval.* The requirements for the label approval of meat and meat food products in part 412 of this chapter, also apply to the labeling of fish and fish products.

PART 544—FOOD INGREDIENTS PERMITTED

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 544.1 Use of food ingredients.

(a) No fish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in part 424 of this chapter, or in this part or elsewhere in this subchapter, or by the Administrator in specific cases.

(b) [Reserved]

[80 FR 75616, Dec. 2, 2015]

PART 548—PREPARATION OF PRODUCTS

Sec.

548.1 Preparation of fish products.

548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

548.4 [Reserved]

548.5 Ready-to-eat fish products.

548.6 Canning and canned products.

548.7 Use of new animal drugs.

548.8 Polluted water contamination at establishment.

548.9 Accreditation of non-Federal chemistry laboratories.

AUTHORITY: 7 U.S.C. 1633; 21 U.S.C. 601–602, 606–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 548.1 Preparation of fish products.

(a) All processes used in preparing any fish product in official establishments shall be subject to inspection by

Program employees unless such preparation is conducted as or consists of operations that are exempted from inspection under 9 CFR 303.1. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. To carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to ensure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter.

§ 548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

All ingredients and other articles used in the preparation of any fish product must be clean, sound, healthful, wholesome, and otherwise such as will not result in the product's being adulterated.

§ 548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

§ 548.4 [Reserved]

§ 548.5 Ready-to-eat fish products.

Ready-to-eat fish products are subject to the requirements in part 430 of this chapter.

§ 548.6 Canning and canned products.

The requirements for canning and canned products in 9 CFR part 431 apply to fish products that are canned.

[80 FR 75616, Dec. 2, 2015, as amended at 83 FR 25325, May 31, 2018]

§ 548.7 Use of new animal drugs.

Edible tissues of fish with residues exceeding tolerance levels specified in 21 CFR part 556 or established in an import tolerance under 21 U.S.C. 360b(a)(6) are adulterated within the meaning of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act because they bear or contain a new animal drug that is unsafe within the meaning of section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 548.8 Polluted water contamination at establishment

In the event that there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of the products that have been rendered adulterated by the water must be condemned. After the polluted water has receded from the establishment, the establishment must follow the cleaning and sanitizing procedures in § 318.4 of this chapter.

§ 548.9 Accreditation of non-Federal chemistry laboratories.

A non-Federal analytical laboratory that has met the requirements for accreditation specified in 9 CFR part 439 and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of regulatory samples is to be made by the establishment using the accredited laboratory.

PART 549 [RESERVED]

PART 550—RECORDS REQUIRED TO BE KEPT

Sec.

- 550.1 Records required to be kept.
- 550.2 Place of maintenance of records.
- 550.3 Record retention period.

§ 550.1

550.4 Access to and inspection of records, facilities and inventory; copying and sampling.

550.5 Registration.

550.6 Information and reports required from official establishment operators.

550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 550.1 Records required to be kept.

The requirements in 9 CFR 320.1 for records to be kept apply to persons that engage in businesses relating to fish and fish products as they do to persons that engage in businesses relating to the carcasses, parts, or products of other species amenable to the FMIA.

§ 550.2 Place of maintenance of records.

The requirements in 9 CFR 320.2 for the place where records are to be maintained apply in the keeping of records under this part.

§ 550.3 Record retention period.

The record retention requirements in 9 CFR 320.3 apply to records required to be kept under this part.

§ 550.4 Access to and inspection of records, facilities and inventory; copying and sampling.

The provisions of 9 CFR 320.4 apply to businesses dealing in fish and fish products.

§ 550.5 Registration.

The registration requirements in 9 CFR 320.5 apply to persons engaging in businesses, in or for commerce, relating to fish and fish products as they do to persons engaging in businesses relating to the carcasses, parts, and products, or any livestock, of other animal species that are amenable to the FMIA.

§ 550.6 Information and reports required from official establishment operators.

The information and reporting requirements in 9 CFR 320.6 for operators of official establishments apply with respect to fish and fish products as

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they do with respect to other species amenable to the FMIA.

§ 550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

The requirements in 9 CFR 320.7 for reports by consignees of allegedly adulterated or misbranded products apply with respect to fish and fish products as they do with respect to products of other species amenable to the Act.

PART 552—EXPORTS

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.

(a) The manner of affixing stamps and marking products for export is that prescribed in § 322.1(a) of this chapter.

(b) The requirements for the issuance of export certificates are as prescribed in § 322.2 of this chapter.

(c) The requirements for clearing vessels and other transportation vehicles are set out in § 322.4 of this chapter.

[80 FR 75616, Dec. 2, 2015]

PART 555—TRANSPORTATION OF FISH PRODUCTS IN COMMERCE

Sec.

555.1 Transportation of fish products.

555.2 Fish product transported within the United States as part of export movement.

555.3 Unmarked, inspected fish product transported under official seal between official establishments for further processing; certificate.

555.4 Handling of fish products that may have become adulterated.

555.5 Transportation of inedible fish product in commerce.

555.6 Certificates.

555.7 Official seals; forms, use, and breaking.

555.8 Loading or unloading of fish products in sealed transport conveyances.

555.9 Diverting of shipments.

555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

555.11 Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter.

555.12 Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 555.1 Transportation of fish products.

(a) No person may sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any fish or fish product that is capable of being used as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except otherwise provided in this paragraph or in part 557 of this subchapter.

(b) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, fish products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 560.3 of this subchapter, any fish product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated.

(c) Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment.

(d) The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Agency's discretion and shall be adequate to determine if fish product in such conveyance is, or when moved could become, adulterated.

(e) Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that fish product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected.

Fish product placed in any means of conveyance that is found by the inspector to be in such condition that the fish product may have become adulterated shall be removed from the means of conveyance and handled in accordance with part 539 or § 540.3 of this subchapter.

§ 555.2 Fish product transported within the United States as part of export movement.

When any shipment of any fish product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

§ 555.3 Unmarked, inspected fish product transported under official seal between official establishments for further processing; certificate.

The requirements governing transportation of fish product that has been inspected and passed, but not so marked, from one official establishment to another official establishment are the same as those in § 325.5 of this chapter that apply to unmarked inspected meat products.

§ 555.4 Handling of fish products that may have become adulterated.

The provisions of § 325.10 of this chapter regarding the handling of products that may have become adulterated or

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misbranded apply to fish and fish products.

§ 555.5 Transportation of inedible fish product in commerce.

The provisions in § 325.11(e) of this chapter regarding the transportation of inedible livestock products apply to the transportation of inedible fish parts or products.

§ 555.6 Certificates.

The provisions in § 325.14 of this chapter regarding the filing of original certificates of unmarked inspected meat products delivered to carriers applies with respect to fish and fish products.

§ 555.7 Official seals; forms, use, and breaking.

The official seals required by this part are those prescribed in § 541.3 and § 312.5 of this chapter.

§ 555.8 Loading or unloading of fish products in sealed transport conveyances.

The requirements in 9 CFR 325.17 governing the unloading of any meat or meat food product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any means of conveyance after the product leaves an official establishment are applicable to fish and fish products.

§ 555.9 Diverting of shipments

(a) Shipments of inspected and passed fish products that bear the inspection legend may be diverted from the original destination without a reinspection of the articles if the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15 of this chapter.

(b) In case of a wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such

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cases the carrier must immediately report the facts by telephone or telegraph to the District Manager in the area in which the emergency occurs. The report must include the following information:

- (1) Nature of the emergency.
- (2) Place where seals were broken.
- (3) Original points of shipment and destination.
- (4) Number and initial of the original car or truck.
- (5) Number and initials of the car or truck into which the articles are reloaded.
- (6) New destination of the shipment.
- (7) Kind and amount of articles.

§ 555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

- (a) To specimens of product sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;
- (b) To material released for educational, research, and other nonfood purposes, as prescribed in § 540.2 of this subchapter;
- (c) To tissues for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in § 540.2 of this subchapter;
- (d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and
- (e) To articles that are naturally inedible by humans.

§ 555.11 Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless the fish and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 550 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by FSIS as one that imposes requirements at least equal to the Federal requirements for purposes of section 301(c) of the Act;

(b) Buy in commerce or import any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 550 of this subchapter, or is the operator of an establishment inspected as required by paragraph (a) of this section and such fish or parts of fish are to be delivered to establishments eligible to receive them under paragraph (a) of this section;

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided*, That any such dead, dying, or diseased fish, or parts of fish may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier must immediately report the facts by telephone or other electrical or electronic means to the Office of Investigation, Enforcement and Audit, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) Load into any means of conveyance containing any dead, dying, or diseased fish, or parts of fish that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any fish or

parts of fish not within the foregoing description or any other products or other commodities.

§ 555.12 Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported.

All vehicles and other means of conveyance used by persons subject to § 555.11 for transporting in commerce or importing, any dead, dying, or diseased fish or parts of fish that died otherwise by slaughter must be leak proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance used in conveying the fish or parts of fish must be cleaned and disinfected before being used in the transportation of any product intended for use as human food. The cleaning procedure must include the complete removal from the means of conveyance of any fluid, parts, or product of dead, dying, or diseased fish and the thorough application of a disinfectant approved by the Administrator to the interior surfaces of the cargo space.

PART 557—IMPORTATION

Sec.

- 557.1 Definitions; application of provisions.
- 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.
- 557.3 No fish or fish product to be imported without compliance with applicable regulations.
- 557.4 Imported fish and fish products; foreign certificates required.
- 557.5 Importer to make application for inspection of fish and fish products for entry.
- 557.6 Fish and fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.
- 557.7 Products for importation; movement prior to inspection; handling; bond; assistance.
- 557.8 Import fish and fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.
- 557.9 [Reserved]
- 557.10 Samples; inspection of consignments; refusal of entry; marking.
- 557.11 Receipts to importers for import fish and fish products samples.

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- 557.12 Foreign canned or packaged fish and fish products bearing trade labels; sampling and inspection.
- 557.13 Foreign fish and fish products offered for importation; reporting of findings to Customs.
- 557.14 Marking of fish products and labeling of immediate containers thereof for importation.
- 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.
- 557.16 Small importations for importer's own consumption; requirements.
- 557.17 Returned U.S. inspected and marked fish and fish products.
- 557.18 Fish and fish products offered for entry and entered to be handled and transported as domestic; exception.
- 557.19 Specimens for laboratory examination and similar purposes.
- 557.20–557.23 [Reserved]
- 557.24 Appeals; how made.
- 557.25 Disposition procedures for fish and fish product condemned or ordered destroyed under import inspection.
- 557.26 Official import inspection marks and devices.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 557.1 Definitions; application of provisions.

(a) When used in this part, the following terms shall be construed to mean:

(1) *Import*. To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer for entry*. Presentation of the imported product by the importer to the Program for reinspection.

(3) *Entry*. The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with § 557.26 of this subchapter.

(b) The provisions of this part shall apply to fish and fish products that are capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in part 94 of chapter I of this title.

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§ 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

(a) The requirements in 9 CFR 327.2(a)(1), (a)(2)(i), (a)(2)(ii)(C)–(I), (a)(2)(iii)–(iv), and (a)(3), for determining the acceptability of foreign meat inspection systems for the importation of meat and meat food products into the United States, apply in determining the acceptability of foreign fish inspection systems for the importation of fish and fish products into the United States. In determining the acceptability of these systems, the Agency will evaluate the manner in which they take into account the conditions under which fish are raised and transported to a processing establishment.

(b) The countries eligible to export specific process categories of fish and fish products are listed at <http://www.fsis.usda.gov/importlibrary>. Such products must be covered by foreign inspection certificates of the country of origin as required by § 557.4. Products from such countries are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part.

[80 FR 75616, Dec. 2, 2015, as amended at 84 FR 59681, 59685, 59689, Nov. 5, 2019; 84 FR 65269, Nov. 27, 2019]

§ 557.3 No fish or fish product to be imported without compliance with applicable regulations.

No fish or fish product offered for importation from any foreign country shall be admitted into the United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

§ 557.4 Imported fish and fish products; foreign certificates required.

(a) Except as provided in § 557.16, each consignment containing any fish or fish products consigned to the United States from a foreign country must be accompanied by an electronic foreign inspection certificate or a paper foreign inspection certificate for fish and fish products. The certificate must have been issued by an official of the

foreign government agency responsible for the inspection and certification.

(b) An official of the foreign government must certify that any fish or fish product described on any official certificate was produced in accordance with the regulatory requirements in § 557.2.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

- (1) The date;
- (2) The foreign country of export and the producing foreign establishment number;
- (3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;
- (4) The product's description, including the process category, the product category, and the product group;
- (5) The name and address of the importer or consignee;
- (6) The name and address of the exporter or consignor;
- (7) The number of units (pieces or containers) and the shipping or identification;
- (8) The net weight of each lot;
- (9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

§ 557.5 Importer to make application for inspection of fish and fish products for entry.

(a) Applicants must submit an import inspection application, to apply

for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted, electronically or on paper, to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 557.16 and 557.17.

§ 557.6 Fish and fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a)(1) Except as provided in §§ 557.16 and 557.17, all fish and fish products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic system.

(b) Fish and fish products required by this part to be inspected must be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application

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must be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and must include all information called for by that form.

(d) Approval for Federal import inspection must be in accordance with §§ 304.1 and 304.2 of this chapter. Also, before approval is granted, the establishment must have developed written Sanitation Standard Operating Procedures in accordance with part 416 of this chapter.

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 307.1, 307.2(b), (d), (f), (h), (k), and (l) and 416.1 through 416.6 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment, provided that an application has been filed in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products in-

spected and passed for entry at the establishment.

(i) A product examination must be made, as provided in paragraph (a) of this section, of a foreign fish or fish product, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh fish shall be the same as those used for domestic fish or fish products. Samples may be collected at no cost to FSIS and submitted to an FSIS laboratory for analysis (See § 557.18).

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product to Program personnel at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with § 318.309(d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(c), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this chapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with § 318.309(d)(1)(i) of this chapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from the Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 557.7 Products for importation; movement prior to inspection; handling; bond; assistance.

The requirements in 9 CFR 327.7 respecting the movement or conveyance from any port, or delivery to the consignee, of any product required to be inspected under part 327, apply to fish and fish products.

§ 557.8 Import fish and fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.

Compartments of ocean vessels, railroad cars, and other means of conveyance transporting any fish or fish product to the United States, and all trucks, chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any fish or fish product offered for importation into the United States, shall be maintained in a sanitary condition.

§ 557.9 [Reserved]

§ 557.10 Samples; inspection of consignments; refusal of entry; marking.

The provisions in 9 CFR 327.10 governing the taking of samples, the inspection of consignments, the refusal of entry, and the controlled pre-stamping of shipments of meat and meat food products apply with respect to fish and fish products.

§ 557.11 Receipts to importers for import fish product samples.

FSIS will issue to importers official receipts for samples of foreign products collected for laboratory analysis, as provided in § 327.11 of this chapter.

§ 557.12 Foreign canned or packaged fish and fish products bearing trade labels; sampling and inspection.

Foreign canned or packaged fish and fish products bearing on their immediate containers trade labels that have or have not been approved in accordance with the regulations in § 541.7 of this subchapter are to be sampled and inspected in the same manner as provided by § 327.12 of this chapter for foreign canned meat food products.

§ 557.13 Foreign fish and fish products offered for importation; reporting of findings to Customs.

Program inspectors are to report their findings as to any fish or fish products that have been inspected in accordance with this part in the same manner as that provided by § 327.13 of this chapter for meat products. Fish and fish products that are refused entry are to be handled in the same manner as provided by § 327.13 of this chapter for meat products that are refused entry. Import personnel will identify to the Port Director of U.S. Customs and Border Protection and the Importer of record any products refused entry into the United States.

§ 557.14 Marking of fish and fish products and labeling of immediate containers thereof for importation.

The regulations in 9 CFR 327.14 governing the marking of meat and meat food products and the labeling of immediate containers of those products for importation apply with respect to fish and fish products.

§ 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

The requirements in 9 CFR 327.15 governing the marking and labeling of outside containers of meat and meat food products apply also with respect to fish and fish products.

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§ 557.16 Small importations for importer's own consumption; requirements.

The exemption in 9 CFR 327.16 for small importations of meat or meat food products for the importer's own consumption applies with respect to fish or fish products.

§ 557.17 Returned U.S. inspected and marked fish and fish products.

U.S. inspected and passed and so marked fish products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification of and approval by the Assistant Administrator, Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

§ 557.18 Fish or fish products offered for entry and entered to be handled and transported as domestic; exception.

The regulations in 9 CFR 327.18 governing the offer for entry into the United States of meat and meat food products apply with respect to fish and fish products. Products that fail to meet these regulatory requirements are subject to penalties as administered by the U.S. Port Director of Customs and Border Protection. Likewise, the products may be subject to detention and to being proceeded against as determined by the Administrator.

§ 557.19 Specimens for laboratory examination and similar purposes.

Importation of fish or fish product samples for trade show exhibition, laboratory examination, research, evaluative testing, trade show exhibition, or other scientific purposes are subject to the same conditions as imported meat or meat product specimens under § 327.19 of this chapter.

§ 557.20–557.23 [Reserved]

§ 557.24 Appeals; how made.

An appeal from a decision of any Program employee is to be made as provided by 9 CFR 327.24.

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§ 557.25 Disposition procedures for fish and fish products condemned or ordered destroyed under import inspection.

Disposition procedures for condemned fish or fish products ordered destroyed under import inspection are as those for carcasses, parts, meat, and meat food products under 9 CFR 327.25.

§ 557.26 Official import inspection marks and devices.

The official inspection legend and other marks to be applied to imported fish and fish products are as required by 9 CFR 327.26 for meat food products prepared from cattle, sheep, swine, and goats.

PART 559—DETENTION, SEIZURE, CONDEMNATION

Sec.

559.1 Fish and other articles subject to administrative detention.

559.2 Articles or fish subject to judicial seizure and condemnation.

559.3 Criminal offenses.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 559.1 Fish and other articles subject to administrative detention.

The provisions of 9 CFR 329.1 through 329.5 governing the administrative detention of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§ 559.2 Articles or fish subject to judicial seizure and condemnation.

The provisions of 9 CFR 329.6 through 329.8 governing the judicial seizure and condemnation of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§ 559.3 Criminal offenses.

The criminal provisions of the Act apply with respect to the inspection of fish and fish products as they do with respect to the inspection of other food products subject to the Act.

PART 560—STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS

Sec.

560.1 Cooperation with States and Territories.

560.2 Cooperation of States in Federal programs.

560.3 Cooperation of States for the Interstate Shipment of Fish and Fish Products.

560.4 Designation of States under the Federal Meat Inspection Act.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 560.1 Cooperation with States and Territories.

The provisions in § 321.1 of this chapter authorizing the Administrator to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering a meat inspection program for the State or Territory apply with respect to fish and fish products inspection.

§ 560.2 Cooperation of States in Federal programs.

Under the “Talmadge-Aiken Act” of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of any State in carrying out Federal functions under the FMIA, including functions relating to the inspection of fish and fish products. A cooperative program for this purpose is called a Federal-State program.

§ 560.3 Cooperation of States for the Interstate Shipment of Fish and Fish Products.

The provisions in § 321.3 authorizing the Administrator to coordinate with States that have meat inspection programs as provided in § 321.1 of this chapter to select certain establishments operating under these programs to participate in a cooperative program

to ship products in interstate commerce apply with respect to fish and fish products inspection.

§ 560.4 Designation of States under the Federal Meat Inspection Act.

The requirements in part 331 of this chapter apply with respect to fish and fish products inspection, including:

(a) The requirements in 9 CFR 331.3 governing the designation of States for Federal inspection under section 301(c) of the Act (21 U.S.C. 661(c));

(b) The requirements in 9 CFR 331.5 governing the designation under section 301(c) of the Act of establishments whose operations would clearly endanger the public health; and

(c) The requirements in 9 CFR 331.6 governing the designation of States under section 205 of the Act.

PART 561—RULES OF PRACTICE

Sec.

561.1 Rules of practice governing inspection actions.

561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 561.1 Rules of practice governing inspection actions.

The rules of practice in part 500 of this chapter, governing inspection actions taken by FSIS with respect to establishments and products, apply to actions taken with respect to fish slaughter, fish processing, fish, and fish products regulated under this subchapter.

§ 561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

The procedures that the Agency must follow before reporting a violation of the Federal Meat Inspection Act for prosecution by the Department of Justice are given in part 335 of this chapter.